Application No.	Applicant(s)	
09/885,445	FRATER ET AL.	
Examiner	Art Unit	
Kathryn Odland	3743	

Interview Summary	09/885,445	FRATER ET AL.
interview Summary	Examiner	Art Unit
	Kathryn Odland	3743
All participants (applicant, applicant's representative, PTO	personnel):	
(1) <u>Kathryn Odland</u> .	(3) <i>Paul Brown</i> .	
(2) <u>Henry Bennett</u> .	(4) Frater et al. via telephone.	
Date of Interview: 12 10 03		
Type: a)⊠ Telephonic b)□ Video Conference c)⊠ Personal [copy given to: 1)□ applicant 2	2)⊠ applicant's representative	1
Exhibit shown or demonstration conducted: d)☐ Yes If Yes, brief description:	e)⊠ No.	
Claim(s) discussed: 1,23 proposed 127-133		
Identification of prior art discussed: Vinegas US 5.	074,2917	
Agreement with respect to the claims f)☐ was reached. g		/A.
Substance of Interview including description of the general reached, or any other comments:	•	
(A fuller description, if necessary, and a copy of the amendallowable, if available, must be attached. Also, where no coallowable is available, a summary thereof must be attached	opy of the amendments that w	
THE FORMAL WRITTEN REPLY TO THE LAST OFFICE A INTERVIEW. (See MPEP Section 713.04). If a reply to the GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR FORM, WICHEVER IS LATER, TO FILE A STATEMENT OF Summary of Record of Interview requirements on reverse signal.	last Office action has already THE MAILING DATE OF THIS F THE SUBSTANCE OF THE	been filed, APPLICANT IS SINTERVIEW SUMMARY
Proposed claum amendments to del	fine over Venegas.	Applicant's
pontrupated na telephone. Applica	ent was adused t	bo incorporate
structural features to define or	ver the prior an	of record.
Proposed amendment is attach		ennett ent Examiner 9700

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

hathan Idland
Examined signature, if required

#### **Summary of Record of Interview Requirements**

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

#### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by
  attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does
  not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
  - (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### **Examiner to Check for Accuracy**

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

FRATER et al.

Atty. Ref.: 4398-169; Confirmation No. 2733

Appl. No. 09/885,445

Group: 3743

Filed: June 21, 2001

Examiner: Kathryn P. Ferko

For: MASK WITH GUSSET

\* \* \* \* \* \* \* \* \* \*

**DRAFT** 

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

## **AMENDMENT**

In response to the Office Action dated July 25, 2003, please amend the aboveidentified application as follows:

## **AMENDMENTS TO THE CLAIMS:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

- 1-22. Canceled
- 23. (Currently Amended) A mask for delivering breathable gas to a patient user, comprising:

a mask shell having a portion adapted to receive a supply of pressurized breathable gas and a user side;

a gusset portion having a first side attached to the user side of the shell and having a second side;

a cushion having a first portion constructed and arranged to attach to the second side of the gusset portion and a second portion constructed and arranged to contact a user's face in use and provide a seal between the mask and the user's face; and

a headgear constructed and arranged to attach the mask shell to the user;

wherein[[,]] the gusset portion is constructed and arranged such that it can expand and eontract be selectively moved within a range of displacement to alter be set at a distance between the mask shell and the cushion, the gusset portion defining a gusset area exposed to the supply of pressurized breathable gas in use such that the supply of pressurized breathable gas acting on the gusset area provides a component of a contact force  $F_c$  of the cushion on the user's face, the force  $F_c$  being maintained in approximately constant proportion to the pressure of the supply of pressurized breathable gas, and a total force of the mask on the face  $F_m$  being maintained within a range of about 35-108 grams per gf/cm<sup>2</sup> pressure of the supply of pressurized breathable gas to

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thereby maintain the seal between the mask and the user's face over an operating pressure range of the mask, including a minimum pressure of the operating pressure range.

- 24. (Original) A mask for delivering breathable gas to a patient as in claim 23, wherein the force  $F_m$  is maintained within a range of about 40-88 grams per gf/cm<sup>2</sup> pressure of the supply of pressurized breathable gas.
- 25. (Original) A mask for delivering breathable gas to a patient as in claim 24, wherein the force  $F_m$  is maintained within a range of about 50-88 grams per gf/cm<sup>2</sup> pressure of the supply of pressurized breathable gas.
- 26. (Original) A mask for delivering breathable gas to a patient as in claim 25, wherein the operating pressure range is about 4-25 gf/cm<sup>2</sup>.
- 27. (Original) A mask for delivering breathable gas to a patient as in claim 26, wherein the expansion and contraction of the gusset portion permits a seal to be maintained between the cushion and the user's face within a range of about plus and minus 8 degrees angular displacement of the mask shell with respect to the user's face.
- 28. (Original) A breathable gas mask arrangement as in claim 23, wherein the gusset portion includes a single gusset having a flexible sidewall with a generally triangular cross-

section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section when exposed to the supply of pressurized breathable gas.

- 29. (Original) A breathable gas mask arrangement as in claim 23, wherein the gusset portion includes a sidewall having a thickened cross-section at a base of the sidewall.
- 30. (Original) A breathable gas mask arrangement as in claim 29, wherein the thickened portion has a generally uniform thickness.
- 31. (Original) A breathable gas mask arrangement as in claim 29, wherein the gusset portion includes a sidewall having a cross-sectional thickness tapering from a thickened base portion to a thinner portion.
- 32. (Original) A breathable gas mask arrangement as in claim 23, and further including a generally rigid backstop attached to the mask shell for contacting a first sidewall portion of the gusset portion to limit movement of the first sidewall portion.
- 33. (Original) A breathable gas mask arrangement as in claim 32, wherein the generally rigid backstop extends around substantially an entire periphery of the gusset portion.

34-124. Canceled

- 125. (Previously Presented) A mask for delivering breathable gas to a patient as in claim 23, wherein the mask is a nasal mask.
- 126. (Previously Presented) A mask for delivering breathable gas to a patient as in claim 23, wherein the mask is a CPAP mask.
- 127. (New) A mask system for delivering breathable gas to a user, comprising:

  a mask shell having a portion adapted to receive a supply of pressurized breathable gas
  and a user side;

a gusset portion having a first side attached to the user side of the shell and having a second side:

a cushion having a first portion constructed and arranged to attach to the second side of the gusset portion and a second portion constructed and arranged to contact a user's face in use and provide a seal between the mask and the user's face; and

a headgear constructed and arranged to attach the mask shell to the user, said headgear including length adjustable headgear straps;

wherein, by selectively varying the length of the headgear straps upon initial set up of the mask system, the gusset portion is movable within a range of displacement to be set at a distance between the mask shell and the cushion, the gusset portion defining a gusset area exposed to the supply of pressurized breathable gas in use such that the supply of pressurized breathable gas acting on the gusset area provides a component of a contact force  $F_c$  of the cushion on the user's face, the force  $F_c$  being maintained to at least equal a minimum sealing force for the seal between the user and the mask at a minimum operating pressure of the mask.

128. (New) A mask for delivering breathable gas to a user, comprising:

a mask shell having a portion adapted to receive a supply of pressurized breathable gas and a user side;

a gusset portion having a first side attached to the user side of the shell and having a second side;

a cushion having a first portion constructed and arranged to attach to the second side of the gusset portion and a second portion constructed and arranged to contact a user's face in use and provide a seal between the mask and the user's face; and

a headgear constructed and arranged to attach the mask shell to the user;

wherein the gusset portion is constructed and arranged such that it can move within a range of displacement to be set at a distance between the mask shell and the cushion, the gusset portion defining a gusset area exposed to the supply of pressurized breathable gas in use such that the supply of pressurized breathable gas acting on the gusset area provides a component of a contact force  $F_c$  of the cushion on the user's face, the force  $F_c$  being maintained in approximately constant proportion to the pressure of the supply of pressurized breathable gas, and a total force of the mask on the face  $F_m$  being maintained within a range of about 35-108 grams per gf/cm<sup>2</sup> pressure of the supply of pressurized breathable gas at a minimum operating pressure of the mask.

129. (New) A mask for delivering breathable gas to a user, comprising:

a mask shell having a portion adapted to receive a supply of pressurized breathable gas and a user side;

a cushion provided to the mask shell and arranged to contact a user's face in use and provide a seal between the mask and the user's face;

a gusset portion provided to the cushion; and

a headgear constructed and arranged to position the mask shell relative to the user;

wherein the gusset portion is constructed and arranged such that it provides a component of a contact force  $F_c$  of the cushion on the user's face, the force  $F_c$  being maintained in approximately constant proportion to the pressure of the supply of pressurized breathable gas, and a total force of the mask on the face  $F_m$  is maintained within a predetermined range to maintain the seal between the mask and the user's face, for at least a minimum operating pressure of the mask.

130. (New) A mask system pressurizable to an operating pressure, the mask system comprising:

a mask frame;

a cushion spaced a distance from the mask frame and structured to transfer a force to a face of a user; and

a gusset portion between the mask frame and the cushion, the gusset portion being constructed and arranged such that at the operating pressure there is an approximately linear relationship between the force and the distance.

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- 131. (New) A mask system as claimed in claim 130, wherein the mask system is structured such that the force on the face increases as the frame is moved closer to the face.
- 132. (New) A mask system pressurizable to an operating pressure, the mask system comprising:

a mask frame;

a cushion spaced a distance from the mask frame and structured to transfer a force to a face of a user; and

a gusset portion between the mask frame and the cushion, the gusset portion being constructed and arranged such that the force and the distance are inversely proportional at a given operating pressure.

133. (New) A mask system as claimed in claim 132, wherein a projected area of the gusset portion is structured to change with a change in the distance.